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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/657,919 | 09/08/2000 | Mark D. Erion | 030727.0035.UTL | 2510 |

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EXAMINER

LEWIS, PATRICK T

ART UNIT PAPER NUMBER

1623

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/657,919

Applicant(s)

ERION ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49, 65-88, 104-118 and 155-158 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-49, 65-88, 104-118 and 155-158 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I wherein the species is etoposide in Paper No. 6 dated June 19, 2002 is acknowledged.
2. Claims 50-64, 89-103, and 119-154 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6 dated June 19, 2003. The restriction requirement was made final in Paper No. 8, dated September 16, 2002.

Objections/Rejections Set For the in Office Action dated September 16, 2002

3. Claims 1-49, 65-88, 104-118 and 155-158 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 95-97, 99-172 and 14 of U.S. Patent 6,312,662 ('662).
4. Claims 1-49, 65-88, 104-118 and 155-158 were rejected under 35 U.S.C. 103(a)/102(e) as being obvious over the Erion et al. U.S. Patent 6,312,662.
5. Claims 1-49, 65-88, 104-118 and 155-158 were rejected under 35 U.S.C. 103(a) as being obvious over the Erion et al. U.S. Patent 6,312,662.

Applicant's Response dated April 21, 2003

6. In the Response filed April 21, 2003, claims 50-64, 89-103, and 119-154 were canceled and the specification was amended. Applicant presented arguments directed to the rejection of claims 1-49, 65-99, 104-118 and 155-158 under the judicially created doctrine of obviousness-type double patenting; the rejection of claims 1-49, 65-88, 104-118 and 155-158 under 35 U.S.C. 103(a)/102(e); and the rejection of claims 1-49, 65-88, 104-118 and 155-158 under 35 U.S.C. 103(a). An action on the merits of claims 1-49, 65-88, 104-118 and 155-158 is contained herein below.

7. The rejection of claims 1-49, 65-88, 104-118 and 155-158 under the judicially created doctrine of obviousness-type double patenting is maintained for the reasons of record set forth in the Office Action dated September 16, 2002.

8. The rejection of claims 1-49, 65-88, 104-118 and 155-158 under 35 U.S.C. 103(a)/102(e) is maintained for the reasons of record set forth in the Office Action dated September 16, 2002.

9. The rejection of claims 1-49, 65-88, 104-118 and 155-158 under 35 U.S.C. § 103(a), is maintained for the reasons of record set forth in the Office Action dated September 16, 2002.

Response to Arguments

10. Applicant's arguments filed April 21, 2003 have been fully considered but they are not persuasive.

Applicant argues: 1) that the instantly claimed structure differs from the structure of the '662 patent in terms of M groups; 2) that the instantly claimed compounds and the compounds described by the '662 patent differ in term of the biological activity of the phosphorylated compound; and 3) that the reference to etoposide at columns 32-33 of the '662 patent is not prior art.

The examiner respectfully disagrees with applicant's arguments. The '662 patent teaches: "Oncolytic drugs such as etoposide, topotecan, taxol, etc, that contain a biologically important hydroxyl or oncolytic drugs such as mitomycin, anthracyclin antibiotics (e.g. dioxorubicin) that contain a biologically important amino group or oncolytic drugs that contain a sulfhydryl moiety are suitable drugs for conversion to compounds of formula 1". See column 32, lines 45-67; column 33, lines 1-15; columns 6-7. The compounds of the '662 patent and the compounds of the instantly claimed invention are both seen to read upon structures wherein the M group is etoposide. Since the Office does not have the facilities for preparing the claimed materials and comparing when with prior art inventions, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). In regards to the exclusion of portions of the '662 patent as prior art, the '662 patent has a different inventive entity and is a continuation-in-part of Application No. 09/263,976, filed on March 5, 1999. The instantly claimed invention does not have the benefit of priority beyond the September 8, 1999 filing date of Provisional Application 60/153,128. In the absence of some proof of a secondary

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nature to obviate the rejection as set forth in the Office Action dated September 16, 2002, or of some specific limitations which would tip the scale of patentability in favor of the instantly claimed invention, the instantly claimed compounds are indeed obvious in view of the prior art.

Conclusion

11. Claims 1-49, 65-88, 104-118 and 155-158 are pending. Claims 1-49, 65-88, 104-118 and 155-158 are rejected. No claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

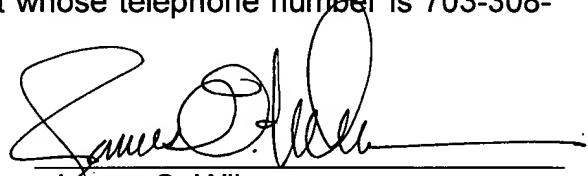
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623


James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

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June 29, 2003